DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

COPY

April 28, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-16

Michael K. Powers
Hospital Administrator
Fairbanks Memorial Hospital
1650 Cowles Street
Fairbanks, Alaska 99701

WARNING LETTER

Dear Mr. Powers:

During an inspection of Fairbanks Memorial Hospital located at 1650 Cowles Street, Fairbanks, Alaska on March 15 through 19, 1999, our investigator documented violations of Section 501 (a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 211 and 600-680 as follows:

1. Failure to exercise appropriate controls over computer or related systems to assure that changes in records are instituted only by authorized personnel [21 CFR 211.68(b)] in that:

   a. An employee user name and computer password were publicly posted for other employees to use to access the [redacted] Data Management System. During the inspection another employee who did not have an established user name or password was observed obtaining access to the [redacted] Data Management System utilizing the posted user name and password.

   b. Three previous employees, who had terminated employment in 1997 and 1998, still had access to critical and limited [redacted] Data Management System functions on March 18, 1999.

   c. There are no written standard operating procedures or records maintained for over-riding temporary deferrals or removing and then re-entering a permanent deferral in the [redacted] Data Management System.

   d. There are no written standard operating procedures or records maintained for changes made to the critical fields of Name and Date-of-Birth (DOB) in the [redacted] Data Management System.

2. Failure to concurrently maintain a record from which unsuitable donors may be identified so that products from such individuals will not be distributed [21 CFR 606.160(a)(1) and (e)] in that temporary and permanent donor deferrals are not posted to the donor record in the [redacted] Data Management System on the day the deferral information is entered, but rather, the deferral information is posted to the last previous donation date.

3. Failure to maintain and/or follow written standard operating procedures to include all steps to be followed in the collection, processing, storage, and distribution of blood and blood products [21 CFR 606.100(b)] in that:

   a. The Duplicate Donor Report procedure only requires a duplicate donor report to be generated once every four to seven weeks. (No duplicate donor reports were generated between November 14, 1998, and March 18, 1999.)

   b. The Duplicate Donor Report procedure does not include any steps for documenting the investigation and merge of true duplicate donors.

   c. Duplicate Donor Reports are generated under one criterion only: Soundex of the last name with matching DOB. No reports are generated to identify potential duplicate donors with different DOBs. Two donors were discovered to be in the database with incorrect DOBs.

4. Failure to assure employees have the necessary training to assure competent performance of their assigned functions [21CFR 606.20(b)] in that:

   a. An employee, who performs infectious disease testing of donor samples, has not completed any of the blood bank training forms to document completion of training. In addition, there is no documentation that management certified this employee as having been adequately trained and approved to perform infectious disease testing.

   b. The [redacted] Data Management System training procedure requires competency in performing computer operations to be evaluated annually. An employee, who performs donor registration procedures, makes changes to critical demographic fields in the [redacted] Data Management System, and who was observed to have posted a user name and password for public use, had not been re-evaluated since January 26, 1996.

   c. There is no documentation that an employee observed during the inspection to be obtaining donor's vital signs was trained to do so.

   d. There are no written standard operating procedures for training employees in blood collection and EIA testing.

5. Failure to calibrate equipment as prescribed in the standard operating procedures [21 CFR 606.60(a)] in that:

   a. The RPM calibration and timer check of the [redacted] Centrifuge was not performed every 60 days as required in the written procedure and operator's manual. The calibration was not performed in April 1998 and at no time between October 27, 1998 and February 23, 1999.

   b. The [redacted] vital signs monitor was not calibrated every six months as required. The calibration was performed four months late in December 1997; two months late in August 1998; and currently was due in February 1999 and had not been performed.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at this facility. It is your responsibility to assure that this facility is in compliance with all requirements of the federal regulations. At the conclusion of the inspection, Form FDA 483, Inspectional Observations, was issued to and discussed with Susan A. McLane, Director of Emergency and Surgical Services. A copy of this form is enclosed for your information.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Seattle District Office, Attention: Miriam Burbach, Compliance Officer, at the above mailing address.

Sincerely,

Roger L. Lowell
District Director

Enclosure:
Form FDA 483

cc: Vann E. Schaffner, M.D.
Authorized Official
Fairbanks Memorial Hospital
1650 Cowles Street
Fairbanks, Alaska 99701